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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,569	02/27/2008	Karin Klokke	930008-2208	6210
26250 7590 12/23/2010 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER ALAWADI, SARAH				
ART UNIT		PAPER NUMBER		
1619				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary

Application No.

10/577,569

Applicant(s)

KLOKKERS ET AL.

Examiner

SARAH AL-AWADI

Art Unit

1619

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-56 and 60-61 is/are pending in the application.
- 4a) Of the above claim(s) 37,39,46 and 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-36,38,40-45,47,52-56,60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/12/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicants amendments/remarks filed on 10/21/2010.

The Examiner acknowledges the following:

Claims 32-36, 38, 40-45, 47, 52-56 and 60-61 are under Examination.

Claims 40 and 47 are currently amended.

Claim 57 is cancelled.

WITHDRAWN OBJECTIONS/REJECTIONS

Objections

Claim 57 is objected to as failing to further limit the subject matter of the previous claim.

Applicants have cancelled claim 57 therefore said objection is hereby **withdrawn**.

Claim 32 is objected to for a typographical error. In light of Applicant's amendment to the claim, said rejection is hereby **withdrawn**.

Rejections

Claims 45 and 47 are rejected under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In light of Applicants amendments to the claim, said rejection is hereby **withdrawn**.

Claims 32-36, 38, 41, 43-45, 47, 52, 53-55, 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Skinhoj et al. (USPgPub 2002/0034544). However, in the interest of efficiency in citing specific column and line numbers, the disclosure of US 7,070,803 (identical

in disclosure to the PgPub) was cited in the rejection. In light of Applicants arguments the anticipation rejection is hereby **withdrawn**.

Claims 32-36, 38, 41,43-45,,47,52, 53-55, 56-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Mulye et al. United States Patent Application 2005/0129778. In light of Applicants arguments the anticipation rejection is hereby **withdrawn**.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-36, 38, 40,41, 42, 43-45,47,52, 53-56 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye et al. United States Patent Application 2005/0129778 and Lofroth et al. United States Patent Application 2004/0030033.

Mulye et al. teach pharmaceutical coatings for beads, see abstract and paragraph 0017. Such coatings contain controlled release polymers and an inert core, see paragraph 0083. An inner layer contains the water-soluble drug and the outer contains a controlled release polymer, see paragraph 0083. The formulation may contain any other component mixed that is normally present in sustained release polymers, see paragraph 0083. Examples of polymers used with Mulye et al. include polyacrylates such as mixtures of acrylic acid and methacrylate polymers, see paragraph 0090. The polymer can be in the form of an aqueous dispersion, see paragraph 0090. The coating layers may contain additional components such as a mixture of magnesium stearate and silicates such as talc or kaolin, see paragraph 0097. The formulations of Mulye et al. are sprayed onto inert beads using fluid bed coating machines, see paragraph 0028. Mulye et al. teach that auxiliaries such as binders are present with the drug, see paragraph 0078. Examples of suitable water soluble drugs to be used include that of metoprolol tartate, see claim 109. Mulye et al. teach multiple unit dosage forms such as capsules containing beads (pellets), see paragraph 0098. Regarding the amount of fatty acid salt present and the content of the layer silicate present

it would have been within the purview of the skilled artisan to optimize the amounts of each component as MPEP 2144.05 recites, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization."

Mulye et al. does not expressly teach metoprolol or metoprolol succinate.

Lofroth et al. teach dispersions of acrylate polymers. To contain the best spraying conditions, the polymers (Eudragit) are mixed with anti-sticking agents such as talc or stearates, see paragraph 0008. The beads of Lofroth et al. may contain inert cores of silicon dioxide, which active ingredient is deposited, see paragraph 0042. The active ingredients include metoprolol and metoprolol succinate, see paragraph 0065-0066.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include metoprolol and metoprolol succinate into the formulations of Mulye et al. One would have been motivated to do so in view of Mulye et al. which teach incorporating active ingredients which include salts of metoprolol. There would have been a reasonable expectation of success because both Mulye et al. and Lofroth et al. teach the use of pharmaceutical ingredients including metoprolol salts such as metoprolol fumarate.

RESPONSE TO REMARKS

Applicants argue that an inventive element in the claimed process is the step of "pre-mixing" at least one fatty acid salt with one layer silicate prior to addition of the same to an aqueous suspension of film-forming polymers. Neither of the cited references teaches or suggests this method of "pre-mixing" as presently claimed. Applicants point out that the coating is

suitable for an API having a high water-solubility despite the fact that it is a water-based dispersion. This feature is neither taught nor suggested by the references.

In response, the Examiner respectfully submits that MPEP 2144.04 discloses that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results, and the selection of any order of mixing ingredients is *prima facie* obvious. See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), *In re Gibson*, 39 F.2d 975, 5USPQ 230 (CCPA 1930) and *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959).

Applicants argue that the instant invention reduces deposition of the coating on the apparatus during spraying so there is no need to regularly clean the spray nozzle; eliminates agglomeration of the pellets with no intermediate drying steps and achieves zero order release kinetics.

The Examiner respectfully submits that the specification discloses that agglomeration of the polymers is reduced by the use of a mixture of at least two separating agents, but does not specify that the order of the steps is critical, see page 15. The specification discloses that magnesium stearate is added to prevent agglomeration, see page 5. There is no evidence presented that demonstrates criticality to the order of the steps. With regards to the release profile (i.e. zero order release) of the active ingredients, the Examiner respectfully submits that this is a property of the coated formulations and no evidence demonstrating criticality to the order of the steps has been presented. The specification on page 15 discloses that zero-order kinetics can be achieved by using two separating agents, wherein the active-ingredient containing cores are lipophilized so that release can be slowed down. Thus, the Examiner respectfully submits that a *prima facie* case of obviousness exists as MPEP 2144.04 discloses selection of any order of

performing process steps is prima facie obvious in the absence of new or unexpected results demonstrating criticality to the order of the steps, and the selection of any order of mixing ingredients is prima facie obvious.

Lastly, the Examiner respectfully submits that claims 40 and 42 were inadvertently dismissed from the header of the rejection. However, the claims were clearly discussed in the body of the rejection which states "regarding the amount of fatty acid salt present and the content of the layer silicate present it would have been within the purview of the skilled artisan to optimize the amounts of each component as MPEP 2144.05 recites, " where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization."

CONCLUSION

Applicant's arguments/remarks are considered unpersuasive. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/Shanon A. Foley/
Primary Examiner, Art Unit 1619